DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

West Pharmaceutical Services
C/O Mr. Kevin Lentz
Director of Regulatory Affairs/PDS Group
530 Herman O. West Drive
Exton, PA 19341

Re: K141464
Trade/Device Name: NovaGuard SA Safety System
Regulation Number: 21 CFR 880.5860
Regulation Name: Syringe, Anti Stick
Regulatory Class: II
Product Code: MEG
Dated: August 13, 2014
Received: August 15, 2014

Dear Mr. Lentz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Digitally signed by Richard C. Chapman -S
Date: 2014.09.10 12:39:17 -04'00'

for

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K141464

Device Name
NovaGuard SA Safety System

Indications for Use *(Describe)*

Single use device that is indicated for use as an accessory with pre-filled ISO Standard glass syringes to aid in the protection of healthcare professionals, patients who self-inject doctor prescribed medications and individuals that assist self-injecting patients, from accidental needlesticks. The intended patient population is unrestricted and may include children and adults, and parenteral methods of administration.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Food and Drug Administration
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PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K141464

5 510(K) SUMMARY

Device: **NovaGuard SA Safety System**

Company Name:

West Pharmaceutical Services, Inc.
530 Herman O. West Drive
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Contact Person:

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Preparation date: 30 May 2014

Classification:

Classification Name: Piston Syringe (Accessory)
Trade Name: NovaGuard SA Safety System
Common/Usual Name: Anti Stick Syringe
Product Code: MEG
Regulation No.: 21 CFR 880.5860
Class: II
Panel Identification: General Hospital Panel

Predicate Devices:

UltraSafe Passive PLUS Needle Guard (K123743)
Safe'n'Sound Passive Delivery System (K101233)

Device Description:

The proposed device, NovaGuard SA Safety System, is a non-sterile, single use anti needlestick accessory for pre-filled ISO standard glass syringes that are 1ml long with a max needle length of 5/8" The NovaGuard SA Safety System consist of two components, a subassembly (syringe holder, sleeve and spring) and a clip. The proposed device will be assembled along with the pre filled syringe by the pharmaceutical company. Upon completion of the injection, the needle is then covered by the sleeve protecting the user from potential sharps needle stick injury. There is a visual, tactile and audible recognition that the device safety feature has activated.

Indications for use:

Single use device that is indicated for use as an accessory with pre-filled ISO Standard glass syringes to aid in the protection of healthcare professionals, patients who self-inject doctor prescribed medications and individuals that assist self-injecting patients, from accidental needlesticks. The intended patient population is unrestricted and may include children and adults, and parenteral methods of administration.

Substantial equivalence:

Based on the indications for use, technology, design features and principle of operation the proposed device, NovaGuard SA Safety System, is substantially equivalent to the predicate devices, UltraSafe Passive PLUS Needle Guard (K123743) and Safe'n'Sound Passive Delivery System (K101233).

Performance Testing:

Bench testing was performed on the proposed device, NovaGuard SA Safety System. It was confirmed that the device functioned as intended.

Biocompatibility testing performed demonstrates that the NovaGuard SA Safety System, met the requirements of ISO 10993- 1 *Biological evaluation of medical devices- Part 1: Evaluation and testing.* Per this standard, The NovaGuard Safety System is categorized as skin contact with a duration of category A- limited (< 24 h).

Clinical Testing:

As per FDA guidance Medical Devices with Sharps Injury Prevention Features, simulated use studies were conducted on the proposed device, NovaGuard SA Safety System. 528 devices were tested with zero failures for activation for a *"97.5% confident that the true failure rate was no higher than 0.7% and 99.5% confidence that it is no higher than 1 %"* as per the FDA Guidance to ensure that the NovaGuard SA Safety System did not impede or adversely

affect the intended clinical performance of the device, did not activate prematurely under expected conditions of use and provided protection against unintended sharps injury until disposal.

Conclusion:

Based on the indications for use, technology, design features, and principle of operation the proposed device, NovaGuard SA Safety System, is substantially equivalent to predicate devices UltraSafe Passive PLUS Needle Guard (K123743) and Safe'n'Sound Passive Delivery System (K101233).